Remarks

Claims and 7 - 17 are pending. Favorable reconsideration is respectfully requested.

Claims 3, 5 and 6 have been cancelled and the limitations of claims 5 and 6 inserted into claims 16 and 17. Claim 3 has been cancelled as redundant. No new claims are added.

The present invention pertains to a mobile monitor to be worn by a patient subject to atrial fibrillation, and which alerts the patent and/or his physician to atrial irregularities by means of at least three state signals which are generated based on differences between a healthy heart scatter-plot and a scatter-plot generated by monitoring n-successive RR intervals of the patient. The different state signals indicate increasing differences from "normal" and "abnormal" behavior. The state signals may be a plurality of LEDs, a plurality of bars on a bar chart, or a plurality of "pie segments" on a pie chart. However, it is noted that each state signal, consistent with the understanding of this term by one skilled in the art, is essentially a "go-no go" or "on/off" signal. No one skilled in the art, for example, would view a scatter-plot itself as a "state signal".

Claims 16 and 17 have been amended to recite that minimally three state signals are capable of display. Applicants earnestly submit that the prior art cited does not disclose, nor dies it teach or suggest the claimed invention.

Claims 7 - 17 have been rejected under 35 U.S.C. § 103(a) over Gilham U.S. 5,622, 178 ("*Gilham*"), in view of Kamen 5,682,901 ("*Kamen*") and Levitan 6,731,974 ("*Levitan*"). Applicants respectfully traverse this rejection. Applicants, Applicants' European Attorney, and the undersigned attorney have all carefully reviewed the references cited against the claims, and fail to find any indication of a comparison of scatter-plots and generation of state signals indicating deviation of an observed scatter-plot from a normal, healthy heart

scatter-plot.

Gilham, column 4, lines 20 to 26, talks about a system for evaluation of scatter-plot data, including comparison means and difference means to calculate a difference between the (measured) scatter-plot data and stored scatter-plot data (derived from a normal heart). *Gilham* does not say how the result (difference) is further processed and how it is presented to the physician. He does not disclose or suggest the result to be a three- (multi-) level state signal representative of at least three degrees of deviation from a normal heart condition.

Levitan, column 3, line 19 to 36, form a recurrence (scatter) plot (such as shown in Figures 3 and 5 and calculates the mathematical product of two quadruple moments as a "determinant". *Levitan* neither teaches comparing the recurrence plot derived from the heart under examination with that of a normal heart nor forming a multi-level state signal representative of at least three degrees of deviation from a normal heart condition.

The same is true with respect to *Kamen*. Column 2, line 11, to column 3, line 52, refer to the generation and display of a Poincaré (scatter) plot "from which a level of autonomic activity can be determined which corresponds to a level of heart failure". *Kamen* essentially relies on the physician's experience in interpreting the plot. Forming a state signal representative of at least three degrees of deviation from a normal heart condition is neither disclosed nor suggested.

The claim language should make clear that state signals and not a scatter-plot is the visual signal. A scatter-plot or the like is very unlikely to be of value to a patient, since the ordinary patient is not a physician nor is he or she trained to interpret scatter plots. Rather, the device of Applicants' generates easily interpreted state signals, the lowest state of which might be interpreted as "OK - all normal" while the highest might be interpreted as "see your doctor immediately."

If the Examiner believes that any of the references, alone or in combination

generates a scatter-plot, compares the scatter-plot with a normal scatter-plot, and generates a visual state signal corresponding to the difference, the Examiner should point to those portions of the reference with particularity. *Gilham* is the only reference which even mentions a comparison between an observed scatter-plot and a normal scatter-plot. However, neither *Gilham* nor any of the other references discloses, teaches, or suggests comparing scatter-plots and checking for the presence of a prescribed geometrical point structure as required by claims 16 and 17.

While the Examiner states that:

> "Examiner takes the position that although *Gilham* does not explicitly teach of using geometrical point patterns/structures for the purpose of identifying conditions, as taught by *Kamen*, it would have been obvious to one having ordinary skill in the art to modify the system of *Gilham* to add such a feature to provide an enhanced capability of identifying conditions."

Applicants respectfully find this statement to be conclusory and without evidentiary support. The Office must supply evidence to support this conclusion. *In re Soli* 137 USPQ 797 (CCPA 1963); *In re Wagner*, 152 USPQ 552 (CCPA 1967); *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002); *In re Beasley*, Slip Opinion 04-1225; Serial No. 07/636,839 (Fed. Cir. December 7, 2004). Since *Kamen* does not compare healthy versus recorded scatter-plots, there would be no motivation to combine *Kamen* with *Gilham*, and even if combined, the result would still not render the claimed invention obvious, since none of the references teach generation of a visual state signal. If the Examiner disagrees, he is respectfully requested to point to the particular portions of the references which teach a visual state signal. *Kamen*, for example, at most, generates a "correlation dimension". However, that correlation dimension is related only to the observed data file, not by a comparison with the correlation dimension of a healthy subject. *Kamen* is directed to quantifying parasympathetic and sympathetic heart activity and correlating with heart failure in general, not specifically with atrial fibrillation.

Moreover, *Kamen* does not disclose any comparison with a normal scatter-plot, but instead relies on length/width ratios of the patient's scatter-plot to "quantify" the sympathetic and parasympathetic activity. It should be noted that *Kamen* indicates that in many cases, his "quantified' "correlation dimension" was unable to be used in predicting heart failure. *See, e.g.* column 10, lines 20 - 34. The work of *Kamen* would dissuade one from attempting to do what Applicants' have done.

Applicants submit that the claims are patentable over the cited references, and solicit withdrawal of the rejection of record. Since the amendment merely incorporated the limitations of claims 5 and 6 into the main claims, no new issues are raised by virtue of the amendment, and entry is respectfully solicited. Entry is also solicited as the claim amendments are believed to place the claims in condition for allowance and to reduce issues upon appeal, should appeal be necessary.

Applicants submit that the claims are now in condition for Allowance, and respectfully request a Notice to that effect. If the Examiner believes that further discussion will advance the prosecution of the Application, the Examiner is highly encouraged to telephone Applicants' attorney at the number given below.

Respectfully submitted,

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